Medicines & Healthcare products
Regulatory Agency

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25 July 2022

Dear **Sara Van Wouwe**

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **25 July 2022** has been reviewed:

Application reference: **2022072501271142**

Manufacturer organisation: **Guangzhou Wondfo Biotech Co., Ltd.**
Address:
No.8 Lizhishan Road, Science City, Luogang District
Guangzhou
510663
China

Manufacturer registration status: **Registered**

Device(s):

GMDN Code & Term	Status	Comment
49119 - Influenza A/B virus antigen IVD, kit, rapid ICT, clinical	Registered	
51228 - Neisseria gonorrhoeae antigen IVD, kit, rapid ICT, clinical	Registered	
51707 - Beta-haemolytic Group A Streptococcus antigen IVD, kit, rapid ICT, clinical	Registered	
51707 - Beta-haemolytic Group A Streptococcus antigen IVD, kit, rapid ICT, clinical	Registered	
63969 - Treponema pallidum immunoglobulin G (IgG)/IgM antibody IVD, kit, rapid ICT, clinical	Registered	
65665 - Faecal occult blood IVD, kit, rapid ICT, self-testing	Registered	
65847 - HIV1/HIV2 antibody IVD, kit, rapid ICT, clinical	Registered	

Please note this letter does not represent any form of accreditation, certification or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations, you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

1. **company/organisation information e.g. name and address**
2. **additional devices (GMDN code or term)**

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/ discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our Public Access Registration

Database (PARD). In vitro diagnostic medical devices registered as undergoing performance evaluation study are not published on this database.

The account number for your company/organisation is **0000012536.**

Please do not respond directly to this email address. The originating email account is not monitored.

Yours sincerely,

Ngozi Onyeukwu
Device registrations service
Devices division
Medicines and Healthcare products Regulatory Agency